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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/856,717 | | Kenj Asano | 0203-0162P | 3321 |

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| EXAMINER | |
|---|---|
| TATE, CHRISTOPHER ROBIN | |
| ART UNIT | PAPER NUMBER |
| 1654 | |

DATE MAILED: 01/28/2005

17

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/856,717 | ASANO ET AL. | |
| | Examiner | Art Unit | |
| | Christopher R. Tate | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *16*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 4, 2004 has been entered. (Please note that the Notice of Abandonment mailed September 20, 2004 has been vacated since the RCE submitted June 4, 2004 predates the Notice of Abandonment).

Claims 14-34 are presented for examination on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-34 each recite the limitation "said disease" in line 1 of each. There is insufficient antecedent basis for this limitation in these claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-23, 26, 27, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagaoka (JP 7173070 - including esp@cenet Abstract and DWPI Abstract), with evidence provided by Nagaoka (US 2004/0038330 - which claims priority to the teachings of JP 7173070).

A *Lentinus edodes* mycelium extract (claimed as a product-by-process) is claimed as well as pharmaceutical/food/drink compositions thereof, and a method of treating viral diseases such as Hepatitis B and HIV therewith is claimed.

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same steps as instantly claimed, as well as pharmaceutical, drink, oral (food) formulations thereof, and a method of treating viral diseases such Hepatitis B and HIV therewith (see, e.g., esp@cenet Abstract and DWPI Abstract, as well as the full text of US 2004/038330 which is the English equivalent of JP 7173070 -including paragraphs [0009], [0010], [0015] - [0042] and claims). Please note that the other claim limitations (e.g., that the extract has a particular cell activity and/or that it comprises approximate

ranges of various ingredients therein) would be inherent to the *Lentinus edodes* mycelium extract taught by JP 7173070.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 14-18, 23, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagaoka (JP 61103816 - JPAB and DWPI Abstracts).

A *Lentinus edodes* mycelium extract (claimed as a product-by-process) is claimed as well as pharmaceutical compositions thereof, and a method of treating bacterial diseases is claimed.

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium extract having antibacterial (antibiotic) activity when applied to the skin (thus, useful for treating bacterial infections), which is prepared via the same (or essential the same) steps as instantly claimed, as well as pharmaceutical (e.g., cream) formulation thereof (see, e.g., JPAP and DWPI Abstracts). Please note that the other claim limitations (e.g., that the extract has a particular cell activity and/or that it comprises approximate ranges of various ingredients therein) would be inherent to the *Lentinus edodes* mycelium extract taught by JP 61103816.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 14-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Nagaoka (US 6,090,615).

A *Lentinus edodes* mycelium extract (claimed as a product-by-process) is claimed as well as pharmaceutical/food/drink compositions thereof, and a method of treating a tumor therewith.

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same (or essentially the same) steps as instantly claimed, as well as pharmaceutical, drink, oral (food) formulations thereof, and a method of treating tumors therewith (see, e.g., col 1, lines 30-44; col 2, lines 25-63; col 3, lines 6-68; and Example 1, Comparative Examples 1 and 2, Example 4, Comparative Examples 3-4). Please note, if not expressly taught, the other claim limitations (e.g., that the extract has a particular cell activity and/or that it comprises approximate ranges of various ingredients therein) would be inherent to the *Lentinus edodes* mycelium extract taught by US '615.

Therefore, the reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (JP 7173070), Nagaoka (JP 61103816 - JPAB English Abstract), and Nagaoka (US 6,090,615), with evidence provided by Nagaoka (US 2004/0038330 - which claims priority to the teachings of JP 7173070).

The cited references (all by the same inventor) are relied upon for the reasons discussed *supra*. In addition, JP 7173070 teaches that the *Lentinus edodes* mycelium extract is useful against liver cancer (as evidence, see, e.g., claim 5 of US 2004/0038330 - which is the English equivalent of JP 7173070).

It would have been obvious to one of ordinary skill in the art to prepare a therapeutic *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat viral diseases, liver cancer (which is typically a tumorous-type cancer), tumors, and/or bacterial diseases, based upon the beneficial teachings provided by the cited Nagaoka references with respect to such therapeutic activities. The result-effective adjustment in conventional working conditions/parameters (e.g., treating a particular type of viral or bacterial infection/disease and/or providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references as a guide.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to the art rejections over the product-by-process claims above, please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." MPEP 2113. The rejections under both 35 U.S.C. 102 and 103 are proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

**Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654